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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : Birke, F. et al ) Art Unit: 1614  
U.S. Appln. No. : 10/719,125 ) Examiner:  
Confirmation No. : 2235  
U.S. Filing Date : 11/21/2003  
Title of Invention : Pharmaceutical Composition  
Attny. Docket No. : 1/1421

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

October 28, 2004

**TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT**

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A and B) with copies of all references cited therein. This is being submitted pursuant to 37 C.F.R. §1.56 and before the mailing of a first Office Action on the merits, pursuant to 37 CFR § 1.97(b).

It should be noted that the references listed in the Information Disclosure Statement have been cited in the International Search Report (ISR) for PCT/EP 03/12874, which corresponds to the present US application. A copy of that ISR is enclosed herewith.

1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

1.97(e).

Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,



Timothy X. Witkowski  
Attorney for Applicant(s)  
Reg. No. 40,232

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Boehringer Ingelheim Corp.  
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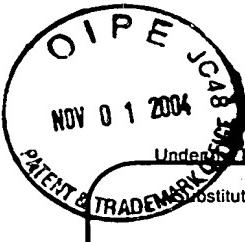
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on October 28, 2004



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Timothy X. Witkowski, Reg. No. 40,232



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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

**(Use as many sheets as necessary)**

Sheet

1

Attorney Docket Number | 1/142

**Complete if Known**

Application Number	10/719,125
Filing Date	11/21/2003
First Named Inventor	Franz BIRKE
Art Unit	1614
Examiner Name	

Examiner Name

## **U. S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

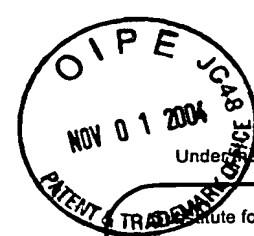
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 97/21670 A1	06/19/1997	BI KG		
		WO 98/11062 A1	03/19/1998	BII GmbH		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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~~Part 2~~ - Continue for form 1449B/PTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

<b>TRADEMA</b> <b>Information Disclosure Statement by Applicant</b> <b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			
<i>(Use as many sheets as necessary)</i>			
Application Number	10/719,125		
Filing Date	11/21/2003		
First Named Inventor	Franz BIRKE		
Art Unit	1614		
Examiner Name			
Sheet	2	of	2
Attorney Docket Number		1/1421	

NON-PATENT LITERATURE DOCUMENTS

<b>Examiner Signature</b>		<b>Date Considered</b>	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**1** Applicant's unique citation designation number (optional) **2** Applicant is to place a check mark here if English language Translation is attached.

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